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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,347	07/12/2006	James Soothill	255352001900	2146

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,347	SOOTHILL ET AL.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *35-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 35-48, a method of therapeutic treatment of a bacterial infection characterized by biofilm formation which comprises administering to a human or non-human animal in need thereof one or more bacteriophages capable of targeting bacteria of said infection and simultaneously, separately or sequentially thereto one or more antibiotics.

Group I, claim(s) 35-48, a method of prophylaxis of a bacterial infection characterized by biofilm formation which comprises administering to a human or non-human animal in need thereof one or more bacteriophages capable of targeting bacteria of said infection and simultaneously, separately or sequentially thereto one or more antibiotics.

Group II, claim(s) 49 and 50, drawn to a bacteriophage selected from the bacteriophage strains NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179, NCIMB 41180 and NCIMB 41181 deposited at the National Collection of Industrial and Marine Bacteria, Aberdeen, United Kingdom, or mutants thereof which retain the ability to target *P. aeruginosa*.

Group III, claim(s) 51-53, drawn to a combined product for simultaneous, separate or sequential administration of a panel of bacteriophages to treat a bacterial infection comprising or consisting of Pseudomonas aeruginosa, each member of said panel having a different strain specificity and wherein said panel consists of two or more bacteriophages selected from NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179, NCIMB 41180, NCIMB 41181 and mutants thereof which retain the ability to target *P. aeruginosa*.

Group IV, claim(s) 54 and 55, drawn to a pharmaceutical composition or one or more bacteriophage selected from the bacteriophage strains NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179, NCIMB 41180 and NCIMB 41181 deposited at the National Collection of Industrial and Marine Bacteria, Aberdeen, United Kingdom, or mutants thereof which retain the ability to target *P.*

aeruginosa, together with a pharmaceutical carrier or diluent, which further comprises one or more antibiotics.

Group V, claim(s) 56 and 57, drawn to a pharmaceutical composition or one or more bacteriophage selected from the bacteriophage strains NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179, NCIMB 41180 and NCIMB 41181 deposited at the National Collection of Industrial and Marine Bacteria, Aberdeen, United Kingdom, or mutants thereof which retain the ability to target *P. aeruginosa*, together with a pharmaceutical carrier or diluent, which further comprises an alginase.

Group VI, claim(s) 58 and 59, drawn to a non-therapeutic method of removing, reducing or preventing bacterial contamination characterized by biofilm formation, said method comprising applying to the site or prospective site of said contamination one or more bacteriophages capable of targeting bacteria of said contamination and simultaneously, separately or sequentially thereto one or more antibiotics or antiseptics.

Group VII, claim(s) 60, drawn to a non-therapeutic method of removing, reducing or preventing bacterial contamination comprising or consisting of *P. aeruginosa*, said method comprising applying to the site or prospective site of said contamination one or more bacteriophages selected from strains NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179, NCIMB 41180 and NCIMB 41181 deposited at the National Collection of Industrial and Marine Bacteria, Aberdeen, United Kingdom, or mutants thereof which retain the ability to target *P. aeruginosa*.

Group VIII, claim(s) 61, drawn to a method of detecting the presence of *P. aeruginos*a in an in vitro sample, which comprises contacting said sample with one or more bacteriophages selected from strains NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179, NCIMB 41180 and NCIMB 41181 deposited at the National Collection of Industrial and Marine Bacteria, Aberdeen, United Kingdom, or mutants thereof which retain the ability to target *P. aeruginosa*, and determining whether said bacteriophage(s) are capable of killing bacteria in said sample.

Group IX, claim(s) 62 and 64, drawn to a method of identifying a bacterial strain selective for one of the bacteriophages NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179, NCIMB 41180 and NCIMB 41181, the method comprising the steps of measuring plaque formation by said bacteriophage in a number of bacterial strains and selecting a strain which allows at least 1000 times more plaque formation by said bacteriophage than by any of said other bacteriophages.

Group X, claim(s) 63, drawn to a bacterial strain identified by a method of identifying a bacterial strain selective for one of the bacteriophages NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179, NCIMB 41180 and

NCIMB 41181, the method comprising the steps of measuring plaque formation by said bacteriophage in a number of bacterial strains and selecting a strain which allows at least 1000 times more plaque formation by said bacteriophage than by any of said other bacteriophages.

Claim 35 is a linking claim, linking the invention of claims 36-48. Further, claim 58 is a linking claim, linking the invention of claim 59. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Additional Election Requirement Applicable to All Groups

Regardless of which group is elected, a further election of invention is required.

Groups I-X, detailed above, read on patentably distinct and specific bacteriophages. Consequently, Applicant is required to elect a specific bacteriophage or combination thereof. Each bacteriophage is patentably distinct because they possess differing biochemical, immunological properties, identifiers and a further restriction is

applied to each Group.

Applicant is advised that examination will be restricted to only the elected antigen and should not be construed as a species election.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-X appear to be bacteriophages. However, Hanlon et al. (Applied and Environmental Microbiology, 2001; 67(6): 2746-2753) disclose bacteriophage penetration through *Pseudomonas aeruginosa* biofilms (see title and abstract).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C.' 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
10/24/08

/Robert A. Zeman/

for Lakia J. Tongue, Examiner of Art Unit 1645